DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL -8 1997

Re: NASCOBAL™
Docket No. 97E-0076

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
U.S. Patent and Trademark Office
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,724,231 filed by Nastech Pharmaceutical Company, Inc. under 35 U.S.C. § 156. The human drug product claimed by the patent is NASCOBAL™ (cyanocobalamin), which was assigned New Drug Application (NDA) No. 19-722.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that it **does not** represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990). For example, BETALIN 12, CORBAVITE, CYANOCOBALAMIN, RUBRAMIN, RUVITE, and VIBISONE contain the same active ingredient as in NASCOBAL™, cyanocobalamin (see attachment).

The NDA was approved on November 5, 1996, which makes the submission of the patent term extension application on January 3, 1997, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

Attachment

cc: Gerald T. Bodner, Esq.
Hoffman & Baron
350 Jerico Turnpike
Jerico, NY 11753

APPROVED DRUG PRODUCTS
with
THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. This volume and accompanying first supplement are current through January 31, 1997.

17TH EDITION

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF MANAGEMENT
DIVISION OF DATABASE MANAGEMENT

1997

COSYNTROPIN

INJECTABLE; INJECTION
CORTROSYN
+ ORGANON 0.25MG/VIAL N16750 001

CROMOLYN SODIUM

AEROSOL, METERED; INHALATION
INTAL
+ FISONS 0.8MG/INH N18887 001 DEC 05, 1985

CAPSULE; INHALATION
INTAL
+ FISONS 20MG N16990 001

CAPSULE; ORAL
GASTROCROM
+ MEDEVA 100MG N19188 001 DEC 22, 1989

CONCENTRATE; ORAL
GASTROCROM
+ MEDEVA 100MG/5ML N20479 001 FEB 29, 1996

SOLUTION; INHALATION
CROMOLYN SODIUM
AN DEY **10MG/ML** **N74209 001** APR 26, 1994

INTAL
AN + FISONS **10MG/ML** **N18596 001** MAY 28, 1982

SOLUTION/DROPS; OPHTHALMIC
CROLOM
+ BAUSCH AND LOMB 4% N74443 001 JAN 30, 1995

SPRAY, METERED; NASAL
NASALCROM
+ FISONS 5.2MG/SPRAY N18306 001 MAR 18, 1983

CROTAMITON

CREAM; TOPICAL
EURAX
+ WESTWOOD SQUIBB 10% N06927 001

LOTION; TOPICAL
CROTAN
AT GALDERMA **10%** **N87204 001**
EURAX
AT + WESTWOOD SQUIBB **10%** **N09112 003**

CUPRIC CHLORIDE

INJECTABLE; INJECTION
CUPRIC CHLORIDE IN PLASTIC CONTAINER
+ ABBOTT EQ 0.4MG COPPER/ML N18960 001 JUN 26, 1986

CYANOCOBALAMIN

GEL, METERED; NASAL
NASCOBAL
+ NASTECH 0.5MG/INH N19722 001 NOV 05, 1996

INJECTABLE; INJECTION
COBAVITE
AP STERIS **0.1MG/ML** **N83013 001**
AP **1MG/ML** **N83064 001**

CYANOCOBALAMIN
AP ELKINS SINN **1MG/ML** **N80515 002**
AP FUJISAWA **0.1MG/ML** **N80557 002**
AP HOECHST MARION RSSL **1MG/ML** **N80564 001**
AP LUITPOLD **1MG/ML** **N80737 001**
AP SOLOPAK **1MG/ML** **N87551 001**
AP STERIS **0.1MG/ML** FEB 29, 1984
AP **0.1MG/ML** **N80573 002**
AP **1MG/ML** **N83120 001**
AP **1MG/ML** **N80573 001**
AP WYETH AYERST **0.1MG/ML** **N83120 002**
AP **1MG/ML** **N80554 001**
N80554 002

RUBRAMIN PC
AP + SQUIBB **1MG/ML** **N06799 004**

RUVITE
AP SAVAGE LABS **1MG/ML** **N80570 002**

CYANOCOBALAMIN

INJECTABLE; INJECTION

	VIBISONE			
AP	FUJISAWA	1MG/ML		**N80557 003**

TABLET; ORAL

	CYANOCOBALAMIN		
+	WEST WARD	1MG	N84264 001

CYANOCOBALAMIN; *MULTIPLE*
SEE ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E
SEE ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PANTOTHENIC ACID; PHYTONADIONE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; VITAMIN A PALMITATE; VITAMIN E
SEE COBALT CHLORIDE, CO-57; CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; INTRINSIC FACTOR

CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; CYANOCOBALAMIN, CO-58

N/A; N/A

	DICOPAC KIT		
	AMERSHAM	N/A;N/A;N/A	N17406 001

CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; INTRINSIC FACTOR

N/A; N/A

	CYANOCOBALAMIN CO 57 SCHILLING TEST KIT		
	MALLINCKRODT	0.1MG;0.5 uCi;60MG	N16635 001

CYANOCOBALAMIN, CO-57

CAPSULE; ORAL

	RUBRATOPE-57		
	BRACCO	0.5-1 uCi	N16089 002

CYANOCOBALAMIN, CO-57; *MULTIPLE*
SEE COBALT CHLORIDE, CO-57; CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; INTRINSIC FACTOR
SEE CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; CYANOCOBALAMIN, CO-58
SEE CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; INTRINSIC FACTOR

CYANOCOBALAMIN, CO-58; *MULTIPLE*
SEE CYANOCOBALAMIN; CYANOCOBALAMIN, CO-57; CYANOCOBALAMIN, CO-58

CYCLACILLIN

TABLET; ORAL

	CYCLACILLIN		
+	TEVA	250MG	N62895 001 AUG 04, 1988
+		500MG	N62895 002 AUG 04, 1988

CYCLOBENZAPRINE HYDROCHLORIDE

TABLET; ORAL

	CYCLOBENZAPRINE HCL		
AB	BARR	10MG	**N73541 001** MAY 23, 1995
AB	DANBURY PHARMA	10MG	**N71611 001** MAY 03, 1989
AB	GENEVA PHARMS	10MG	**N72854 001** NOV 19, 1991
AB	INVAMED	10MG	**N73683 001** FEB 26, 1993
AB	MYLAN	10MG	**N73144 001** MAY 31, 1991
AB	ROYCE LABS	10MG	**N74436 001** NOV 30, 1994
AB	SIDMAK LABS NJ	10MG	**N74421 001** SEP 29, 1995
AB	WATSON LABS	10MG	**N73143 001** NOV 27, 1991
	FLEXERIL		
AB	+ MERCK SHARP DOHME	10MG	**N17821 002**

CYCLOPENTOLATE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

	AK-PENTOLATE		
AT	AKORN	1%	**N85555 001**
	CYCLOGYL		
AT	+ ALCON	0.5%	**N84109 001**
AT	+	1%	**N84110 001**
	+	2%	N84108 001